Pesticide Action Network Europe

A poisonous injection - a study on the process to cumulative risk assessment of pesticides

Brussels, 04-02-14

Contact: H.Muilerman, hans@pan-europe.info, tel. 0031655807255

To: Management Board EFSA/ Mr. Url.

Concerning : PAN Europe study on cumulative risk assessment of pesticide residues.

Dear Mr. Url and member of the Management Board, we herewith send you our new study regarding the process to the implementation of the cumulative risk assessment of pesticide residues as provided by the 2005-Residue Regulation 396/2005. Every day people are exposed to dozens of pesticide residues in food, in fruit and vegetables, and to hundreds of other chemicals during their lifetime. Food standards however are based on a single exposure, which is unrealistic. Consequently these standards do not protect humans against the potential health damage of mixtures especially over an extended period of time. We have expressed our concerns about the slow implementation on the methods to assess cumulative effects by you several times and even 9 (nine!) years after the publication of the Regulation people in Europe are not protected against the harms of cumulative effects. We feel this is totally unacceptable and we started research to find out the reason for this enormous delay is.

Our report, in summary, reveals that one of the main reasons for the delay is industry lobby and industry infiltration in scientific panels at European and international level. And, at the same time, a complete lack of attention of agencies to this kind of unfair practices. Our research shows a well planned and orchestrated attempt of industry to undermine policies meant to evaluate the toxicity of chemicals mixtures (cumulative risk assessment, CRA). This is done by putting industry-linked experts in crucial positions in expert panels of the World Health Organisation (WHO) and of the European Food Safety Authority EFSA.

The WHO was an easy target for industry because industry-linked scientists -who kept their links hidden- could simply outnumber the other attendants in the WHO-panel and impose the industry position on the WHO. Our research shows that out of the WHO-planning group on CRA, 73% of the members were not impartial observers, but rather had industry-links and conflicts of interest, while 5 out of the 6 authors that published the final WHO-framework had strong industry-ties. A handful of industry-linked people therefore managed to dominate the WHO. Remarkably, none of them was an active scientist nor were any involved in developing research.

With regard to the European Food Safety Authority EFSA, industry has taken a similar approach: infiltration by industry-linked experts in EFSA panels and working groups. Of the experts having worked on CRA for EFSA, PAN Europe observed that 19% had a formal relation with industry lobby group ILSI (International Life Sciences Institute) and

that even the majority (52%) had a connection with industry. The same people dominating WHO managed to dominated EFSA on CRA, where they have been found 'fertile ground'. Many national experts and civil servants present in EFSA panels have been in their positions their entire career and were reluctant to change their mindset. Many felt that cumulative mixture toxicity is a non-issue. Therefore, EFSA's work on CRA in the first 6 years has tended to lean towards a position that would qualify mixture toxicity as largely irrelevant and that no extra consumer protection is necessary.
Again, as in the case of the WHO, only a few members of the EFSA panels (22%) were scientists actively carrying out research. An incredibly small number for an institute that claims to base their opinions on science.

It was a bit late, but the credits have to be given to the Health Commissioner who finally intervened and forced you to change course, start a science-based approach and take CRA seriously. Still the EFSA pesticide PPR panel refused to cooperate and in 2012 EFSA terminated the mandate of the panel because of the "lack of significant progress"[1]. At the same time, the European Parliament forced EFSA to adopt a conflict of interest policy, leading to a partial reduction in the membership of infiltrators. The outcomes of these measures remains to be seen, but this is the first example of Commission rolling back a clear example of infiltration by an industry network. It is very remarkable that your organisation apparently was hardly aware of the infiltration and only reacted after the SANCO intervention.

Still industry hasn't given up and continues to try to create credibility for another industry-promoted CRA-tool (probabilistic risk assessment, PRA) by joining forces in the EU funded research program Acropolis. The same industry-linked people that were active in WHO and in EFSA now gather in this program, co-managed by food industry group Freshfel. They promote and defend this tool (PRA) to allow a certain level of health damage to people in an attempt to 'neutralise' the coming policy on CRA, which they were unable to stop. The tool is to "*prove that pesticide use is safe*[2]" according to coordinator Van Klaveren. Acropolis also shows many dual roles, people simultaneously active in developing, advising and implementing tools. The current EFSA science director Juliane Kleiner is a clear example of having dual roles .

PAN Europe notes with pleasure that DG SANCO stopped the unfair practices and infiltration by industry and finally managed to reverse the road taken by EFSA. The work however is not done yet. Especially the new attempt by industry to include probabilistic risk assessment should be stopped and a normal deterministic approach followed.

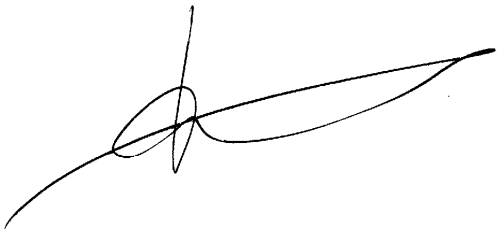
We sadly note that EFSA still has no system in place to counter these infiltrations and apparently no culture to defend independent process and sound science. We would like to encourage you to take lessons from the outcome of our research and develop a stricter policy on infiltrations and unfair orchestrated lobby campaigns. Evaluating declarations of interests of individuals is a first good step but you might still miss the 'big picture'. We therefore would like to raise the attention in EFSA for infiltration and unfair lobbying and create a 'culture of integrity' at all levels. We would like to point at

[1] Minutes from an EFSA/Commission teleconference of 11 July 2012, see , http://www.pan-europe.info/Campaigns/pesticides/cum_syn_effects.html under "useful information".
[2] http://www.acropolis-eu.com/object_binary/o4422_ACROPOLIS_03.pdf

US-EPA who recently appointed a 'science integrity officer' who oversees the policy to increase independence, transparency and professionalism. Training staff on integrity, enhancing rigorous peer-review, and professional development at all levels should be the main roles of such a science integrity officer.
Our recommendations to you are,

- start today with implementing cumulative risk assessment in practice, and revise all ADI's (acceptable daily intakes) and MRL's (maximum residue levels);
- stop including probabilistic risk assessment as a tool for cumulative risk assessment;
- make the policy on conflict of interest more strict in EFSA and include the entire career of a person in the declarations of interests
- increase the attention to orchestrated infiltration attempts (from whatever side) on science and policy; a special unit in EFSA should take care of this, managed preferentially by a *science integrity officer*, reporting directly to the Director;
- start an internal campaign (communication, training) on creating a culture of scientific integrity and professionalism in EFSA.

We hope very much for your reaction.
Yours sincerely,



H. Muilerman,
Pesticide Action Network Europe